

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

In re Search of 110 Terry Drive, Newton, PA; 100 Campus Drive, Buildings 350 and 351, Newtown, PA; and 114 Pheasant Run, Newtown, PA	:	
	:	No. 21-mj-1220
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KVK-Tech, Inc.,	:	The Hon. Harvey Bartle III
Murty Vepuri,	:	
Ashvin Panchal,	:	

UNITED STATES OF AMERICA	:	
	:	No. 21-cr-00132
v.	:	
	:	The Hon. Harvey Bartle III
MURTY VEPURI,	:	
ASHVIN PANCHAL,	:	
KVK-TECH, INC.	:	

**RESPONSE IN OPPOSITION TO GOVERNMENT’S MOTION TO MODIFY THE
COURT’S ORDER RELATED TO FILTER TEAM COMPOSITION**

The government’s Motion represents an astonishing admission. Despite the government’s explicit representations to this Court that it had evidence of an ongoing crime justifying the search warrant, the seizure of millions of documents, and months of nearly-unfettered access to the seized materials, the government Filter Team can identify no reasonable basis to conclude that the Defendants misused a privileged relationship to commit a crime or fraud. Saying the Filter Team lacks the expertise to identify any crime or fraud, the government asks this Court to allow regulatory and compliance specialists from the Food and Drug Administration’s Office of Chief Counsel (“FDA-OCC”) to comb through privileged materials in search of “technical” violations that elude the Filter Team attorneys. Motion at 1-2. The

government cites no precedent authorizing this approach, which would hand the Defendants' privileged materials to their primary regulator.

Why is the government's admission astonishing? The Filter Team, with one exception of whom KVK is aware, consists of DOJ attorneys who are members of or detailed to the DOJ branch that *specializes* in enforcing the Food Drug and Cosmetic Act ("FDCA"), the statute at the center of the investigation (and the pending prosecution).¹ This same branch, per DOJ's Justice Manual, restricts FDA-OCC participation in these matters because DOJ has those specialists.² The one (to KVK's knowledge) Filter Team attorney who is not affiliated with the specialist DOJ branch is one of the most senior AUSAs in the Eastern District of Pennsylvania and well recognized for his ability and experience.³ Yet even this specialized and qualified government team has found no basis for applying the crime-fraud exception.

The government's admission has substantive relevance. First, this resource-intensive and intrusive episode began with the government's repeated assertions that it *already* had evidence of a crime permitting it to seize the privileged information. That was its representation at the search warrant stage and its justification for giving the government immediate access to the seized materials. It is fair to ask how the government could have represented to the Court that KVK was engaged in an ongoing violation of the FDCA when it now tells the Court, months later, that it actually lacks the expertise to identify any violations.

Second, the filter process is not supposed to work this way. Unable to identify any crime

¹ Specifically, they are members of the Department of Justice Consumer Protection Branch ("DOJ-CPB")—the DOJ branch that "oversee[s] and conduct[s] all civil and criminal matters arising under" the FDCA. Justice Manual §4-8.200. U.S. Attorney's Offices enforcing the FDCA must defer to DOJ-CBP's expertise. *See id.*

² *Id.*; see <https://www.fda.gov/about-fda/office-commissioner/office-chief-counsel>.

³ KVK had no objection to this AUSA's addition to the Filter Team, when asked last winter.

or fraud, the government now wants a specialist from FDA-OCC to examine privileged material in hopes of identifying a regulatory violation, “within the context of the FDA’s compliance program.” Motion ¶3.⁴ This proceeding is not, and should not become, a shadow FDA inspection. The FDA is fully capable of inspecting KVK (and has in fact done so within the last year, with no regulatory action taken)—but it may not review KVK’s privileged materials when doing so.

Indeed, the Filter Team’s request threatens to draw this proceeding far afield of its appropriate scope. Whether to pierce the attorney-client privilege based on an alleged crime and fraud should not turn on obscure requirements that even DOJ’s FDCA specialist attorneys cannot identify. It should require no “technical” (Motion at 1-2) regulatory or compliance expertise.⁵ Moreover, the crime-fraud exception does not apply unless the government shows that the privilege holder intentionally misused the privileged relationship to further the wrong alleged. *E.g., In re Grand Jury Matter #3*, 847 F.3d 157, 166 (3d Cir. 2017). This subjective standard cannot be met with a violation so obscure that DOJ-CPB specialist attorneys cannot identify it. KVK notes the irony of this request. The Filter Team wants to accuse KVK and the individual defendants (neither of whom is an attorney, much less a specialist attorney) of intentional violations of the FDCA, when DOJ’s FDCA specialists cannot find even a reasonable basis to believe a crime or fraud occurred.

⁴ In fact KVK quickly rebutted, with documentation easily accessible to the Filter Team, the two crime-fraud theories the Filter Team has already presented to the Special Master.

⁵ For example, the Court had no difficulty analyzing the paperwork deficiencies alleged in Count One of the Superseding Indictment against the statute and regulations, and concluding that they did not support the charged scheme to defraud FDA. Mem. Op., Doc. 131 (Feb. 23, 2022), at 3-17. DOJ’s attempt to construct a felony out of those deficiencies prompted its interlocutory appeal and stayed the May 10, 2022 trial date.

Finally, the government cites no case authorizing a regulatory agency to review a regulated entity's privileged materials in a filter process, and Defendants know of none. As the Court knows, the Third Circuit requires that "an independent DOJ attorney acceptable to the district court" conduct filter review. *In re Search of Elec. Commun. In the Account of chakafattah@gmail.com*, 802 F.3d 516, 530 (3d Cir. 2015) (disapproving initial filter review by non-attorney agents). There is no reason to think the Third Circuit specified "DOJ attorney" thoughtlessly. Opinions allowing the use of filter teams emphasize the importance of walling-off filter attorneys from matters in which protected materials could be used against the privilege holder, as the Court itself did.⁶ *E.g.*, *In re Sealed Search Warrant*, 11 F.4th 1235, 1249 (11th Cir. 2021) (collecting cases); *see* Order, Doc. 87 (Nov. 3, 2021), at 1. Maintaining that wall is at least theoretically possible when reviewers are DOJ attorneys; each can take care not to investigate or prosecute a privilege holder whose protected materials they have reviewed. Yet no such wall is possible with respect to FDA-OCC, which participates in ongoing oversight of regulated products and firms. There is no way to ensure that the Defendants' privileged materials would not inform future FDA-OCC recommendations or actions.

Adding the Defendants' primary regulator to the Filter Team will void their privileges with no justification. That the government considers this "ministerial" (Motion ¶6) reflects a troubling disregard for foundational privileges. Hardly "ministerial," the Motion represents an extraordinary request and the Court should reject it.

⁶ In light of this concern DOJ itself created a "Special Matters Unit" of attorneys who conduct filter review and litigate privilege issues with no enforcement duties. *See* DOJ Fraud Section Year In Review (2020), at 4, available at <https://www.justice.gov/criminal-fraud%20/file/1370171/download>.

CONCLUSION

For these reasons, the Motion should be denied.

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Respectfully submitted,

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Dated: May 31, 2022

CERTIFICATE OF SERVICE

I hereby certify that on this date the Response in Opposition was filed electronically through the CM/ECF system, which will serve it electronically on all counsel of record.

May 31, 2022

/s/ Lisa A. Mathewson
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